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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/019,348	02/05/98	GEORGOPOULOS	K	MGP-042CP2

000959
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HM12/1124

EXAMINER	
LUBET, M	
ART UNIT	**PAPER NUMBER**
1644	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/019,348	Applicant(s) Georgopoulos et al.
	Examiner Lubet	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Aug 24, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-42* is/are pending in the application.

Of the above, claim(s) *1-17* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *18-42* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *11*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-42 are pending.

2. Examiner acknowledges election with traverse of Group XV claims 18-28 and 42 in Paper 10 filed August 24, 1999. Applicant has argued that the invention of Group XVI is not distinct from the invention of XV since a cell which is Aiolos deregulated encompass null or underexpressing mutations at the Aiolos locus. This argument is persuasive and claims 29-42 are rejoined to Group XV. Claims 18-42 are under examination. Claims 1-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded of the proper content of an Abstract of the Disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. The abstract of the disclosure is objected to because the abstract does not disclose the invention claimed. Correction is required.

4. This application lacks the necessary reference to the prior application 08/733,622. A statement reading "This is a divisional of Application No. 08/733,622, filed 10/17/96 ." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all non-provisional parent applications referenced should be included.

5. Claims 18-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Reasons are set forth below.

A. Claims 18, 29 and 35 are unclear because of the recitation of the term "a method of providing an antibody." The claim would read more clearly if it recited a method of making or a method of isolating an antibody. For instance, the claim would read more clearly if it recited a "A method of isolating an antibody comprising isolating an antibody from a mammal having a cell which is Aiolos deregulated or from a cell derived from a mammal having a cell which is Aiolos deregulated."

B. In claim 24, there is not antecedent basis for the term "antigen" in claim 18.

C. In claim 34 there is not antecedent basis for the term "antigen" in claim 29.

D. In claim 18, it is unclear what the term "mammal having a cell which is Aiolos deregulated" means. Is the term limited to animals which have a mutation or deletion in gene encoding Aiolos protein which results in Aiolos protein with abnormal function? Does the term encompass animals in which Aiolos gene is deregulated but the gene encoding Aiolos protein is wild type?

6. Claims 24 and 34 are rejected under 35 U.S.C. 112, first paragraph, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Reasons are set forth below.

It is unpredictable what proteins are homologous with each other because the specification does not give guidance as to how to determine if a protein is homologous with another protein. The specification does not disclose any algorithm for sequence analysis to determine if two proteins are homologous. There is no guidance in the specification as to what allowances to use for gaps and insertions or what weighing factors are given for conservative substitutions. Therefore one with skill in the art would not be able to obtain an antibody to an antigen that is at least 90% homologous to an antigen because one with skill in the art would not be able to determine if two antigens are at least 90% homologous.

In view of the nature of the invention, the state of prior art, the amount of guidance present in the specification, and the breath of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 18, 19, 22, 23, 25-29, 32, 33, 35, 36, 37 and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Frosch et al. (PNAS 82:1194, 1985).

Frosch et al. teach a method of producing a monoclonal antibody by immunizing NZB mice with poorly antigenic antigen, K1 polysaccharide. Frosch et al. teach that K1 polysaccharide is poorly immunogenic in wild type mice, IE Balb/c mice (see abstract). Frosch et al. teach a method of obtaining a monoclonal antibody by immunizing mice with bacteria expressing K1 polysaccharide, isolating lymphocytes from the immunized mice and fusing the cells to produce hybidomas secreting anti-KI antibodies (see page 1195, in particular). Frosch et al. teach that the monoclonal antibody is an IgG antibody (see page 1195, in particular). Frosch et al. teach that NZB mice immunized with a weak antigen produced increased IgG response to antigens when compared to wild type (BALB/c) mice (see page 1197, in particular). Frosch et al. teach that NZB mice is known to exhibit hyperactivity of both its B-cell and T-cell system (see page 1197, in particular).

Frosch et al. is silent as to whether NZB mice are Aiolos deregulated or are homozygous for null or underexpressing mutations at the Aiolos locus. However, NZB mice have the same phenotype as Aiolos deregulated mice, IE they are hyperresponsive in B and T cell compartment, have increased levels of autoantibodies and elevated IgG responses to antigens (see page 96 of the

specification). Therefore, absent data to the contrary, the method of obtaining antibodies taught by Frosch et al. is the same as the instantly claimed method of obtaining antibodies.

The antibody claimed in claim 42 is anticipated by the monoclonal antibody taught by Frosch et al. It is noted that the limitation wherein the antibody is produced by an Aiolos mutant animal or cell does not does not distinguish the antibody from prior art antibodies. The claimed antibody is anticipated by prior art antibodies produced by another strain of mouse or animal.

10. Claims 18-19, 21-29, 31-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frosch et al. (PNAS 82:1194, 1985).

Frosch et al. has been discussed supra. The invention claimed in claims 21, 24, 34, 39 differs from the method of producing antibodies taught by Frosch et al. because Frosch et al. does not obtain antibodies specific for autoantigens or for antigens which are 90% homologous to an endogenous antigen. However, based on the teaching of Frosch et al. who teaches that obtaining antibodies to weak antigens by immunizing NZBmice with weak antigens, one with ordinary skill in the art would be motivated to obtain antibodies to any weak antigen, IE autoantigens or antigens that are highly homologous to self antigens, by immunizing NZB mice with such antigens and obtaining polyclonal or monoclonal antibodies to the antigens as taught by Frosch et al.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

12. Claims 24 and 25 are objected to because the claims contain words that are in bold. Applicant is required to amend claims 24 and 25 to eliminate the bolding of the words.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martha Lubet whose telephone number is (703) 305-7148. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for this group is (703) 305-3014 or 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Martha T. Lubet
Nov. 25, 1999

Christina Chan

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640